

## PE Investment in Health Care Attracting Greater Federal Scrutiny

As Annie Railton, William Harrington and Ashley Drake explain in this edition of their Federal Civil Enforcement column, private equity firms and their counsel should be prepared for heightened FCA scrutiny stemming from their investments in health care companies, and bolster their processes accordingly.

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Private equity investment in health care companies has garnered increasingly critical attention from the federal government, including recent scrutiny by Congress: In March 2021, the Oversight Subcommittee of the U.S. House of Representatives' Ways and Means Committee held a hearing on "Examining Private Equity's Expanded Role in the U.S. Health Care System." The tenor of the hearing is encapsulated in the opening remarks of the Oversight Subcommittee's Chairman, U.S. Representative Bill Pascrell Jr. (D-N.J.), who kicked off the discussion by cautioning that: "It's past time for a bright light to be shined on how private equity ownership and our health care system affects patient safety, cost, and jobs." Noting that 2020 saw \$66 billion in private equity investment across the health care industry—a 21% increase from 2019—Chairman Pascrell expressed concern



that "private equity's main focus—profit—is often at odds with what is best for patient care."

What would that bright light look like? The hearing discussed legislative proposals to increase transparency of private equity ownership and related party transactions. But panelists also discussed a well-established statute, the False Claims Act, that is already a primary tool for federal enforcement actions involving health care fraud. Indeed, the Congressional panel comes at a time when the Department of Justice (DOJ) has recently investigated and penalized private equity owners millions of dollars for false

claims made by their health care portfolio companies, settlements that mark a new development in who is targeted in False Claims Act cases. Taken together, the Congressional hearing and the recent DOJ actions signal compliance priorities for private equity companies investing in health care portfolio companies.

**Private Equity's Investment in Health Care Draws Congressional Scrutiny.** The House Ways and Means Oversight Subcommittee hearing centered on concerns expressed about how private equity's investment model purportedly focuses on maximizing profit to the

detriment of patient welfare, with a particular impact on individuals receiving government-funded health care. Much of the discussion was focused on private equity-owned nursing homes, an industry that has been the focus of significant regulatory scrutiny in recent years and particularly during the COVID-19 pandemic, which had a markedly devastating impact on nursing home residents and staff. Among other things, the subcommittee discussed research done by Prof. Sabrina Howell of NYU Stern School of Business, who testified at the hearing that her research into 1,700 nursing home facilities bought by private equity firms from 2000 to 2017 showed that being admitted to a private equity-owned nursing home increased the short-term probability of death by about 10%, and increased the amount billed to Medicare by 11%.

But the subcommittee's concerns are not limited to nursing homes. Chairman Pascrell remarked that since 2013, at least 25 health care companies have paid settlements totaling over \$570 million for allegedly violating the False Claims Act by defrauding Medicare and Medicaid while under private equity ownership. And the concerns that the testifying witnesses expressed—including concerns about the impact that private equity ownership has on staffing deficiencies, over-billing, and providing unnecessary services—have often been the

focus of health care fraud actions across the industry. Following the hearing, Chairman Pascrell also penned a letter to the Government Accountability Office (GAO) calling for an investigation into the relationship between private equity investments and health care facilities that have closed, citing a purported increase in surprise billings, nursing home mortality rates, and decreasing access to safety net hospitals and other providers.

Additionally, a primary goal of the Congressional hearing was described as a push for increased transparency in terms of ownership of health care companies, including more robust reporting to the Centers for Medicare and Medicaid (CMS) and requiring facilities to seek prior approval before changes in ownership. As the subcommittee made clear, though, a key motivation behind such measures is to increase regulatory oversight and enforcement—as one witness stated, to help “find the fraud.”

### **Increased FCA Risks for Private Equity Investors in Health Care.**

This Congressional hearing comes on the heels of several False Claims Act (FCA) enforcement actions by the DOJ against private equity owners of health care portfolio companies. The FCA is the federal government's primary tool to police federal program fraud. Of particular relevance to private equity owners, the FCA imposes liability not only on those who knowingly submit

material false claims for payment by the U.S. government, but also on any entity or person who *causes* the submission of false claims by another. The health care industry in particular has long been a focus of the DOJ's FCA enforcement activity. In remarks at the ABA Civil False Claims Act and Qui Tam Enforcement Institute on Dec. 2, 2020, Deputy Assistant Attorney General Michael D. Granston noted that of the \$11.4 billion that the DOJ recovered over the last four years in FCA settlements and judgments, approximately 80%—or \$9 billion—was recovered in health care fraud matters.

Health care companies owned by private equity firms have frequently been in regulatory cross-hairs. Until recently, their owners and sponsors have largely avoided FCA scrutiny—but that is no longer the case. Now the government has increased its pursuit of FCA actions against private equity owners on the basis that they are responsible for causing the submission of false claims made by their health care portfolio companies. Two recent settlements illustrate the potentially costly consequences of this effort.

On Sept. 18, 2019, the DOJ announced a \$21.36 million settlement that resolved FCA allegations against compounding pharmacy Diabetic Care Rx, LLC, or Patient Care America (PCA), two PCA officers, and PCA's private equity

owner, Riordan, Lewis & Haden (RLH). The case, *United States ex rel. Medrano and Lopez v. Diabetic Care RX*, marked the first time that the DOJ had intervened in an FCA action against a private equity firm investing in a health care company, and the DOJ described the prosecution and resolution as demonstrating its “continuing commitment to hold all responsible parties to account for the submission of claims to federal health care programs that are tainted by unlawful kickback arrangements.” Specifically, the settlement resolved allegations that from September 2014 to April 2015, PCA paid kickbacks to outside marketing companies to solicit beneficiaries of TRICARE—the government health program for U.S. military members and their families—for prescriptions for expensive compound creams and vitamins, among other alleged misconduct. The DOJ alleged that RLH, which acquired PCA two years before the company entered into the marketing agreements at issue, approved of the decision to use marketers to generate referrals, knew that TRICARE was the source of a majority of PCA’s revenue, received regular financial reports showing the compounding revenue and commissions paid to marketers, and funded \$2 million of the payments to marketers. The complaint alleged that RLH’s purported focus on profit—including its plans to sell the pharmacy in five years—

had propelled it to enter the unlawful business at issue, a concern echoed in the recent House Ways and Means Oversight Subcommittee hearing. The allegations as to RLH also focused specifically on the conduct and knowledge of two RLH partners who served as PCA board members.

On Nov. 19, 2020, the DOJ announced a second FCA settlement with a private equity firm. In *United States ex rel. Johnson v. Therakos*, a Johnson & Johnson (J&J) unit and private equity firm The Gores Group (TGG) agreed to pay a combined \$11.5 million to resolve allegations that between 2006 and 2015, Therakos, a medical device and pharmaceutical manufacturer, engaged in off-label marketing to promote its cancer treatment for use in pediatric patients. Therakos was a J&J subsidiary from 2006 to 2012, at which point it was acquired by TGG. Unlike *Medrano*, there were no specific allegations as to TGG’s involvement in the underlying fraud. Instead, the DOJ alleged only that Therakos’ improper practices continued after TGG acquired Therakos from J&J, and that TGG hired a former Therakos employee as the company’s new CEO.

**What next?** Rather than being outliers, it is likely that these settlements are indicative of other investigations already underway. Indeed, in June 2020, former Acting Assistant Attorney General Ethan Davis, speaking to the Institute for

Legal Reform on DOJ enforcement priorities, remarked that, where appropriate, the DOJ will pursue enforcement actions against private equity firms. Davis noted that this may include private equity firms that invested in companies receiving CARES Act funds, and he also cautioned more broadly that private equity firms may face FCA liability when they take an “active role” in illegal conduct by an acquired company. Davis also emphasized the government’s focus on private equity investments in health care, stating that: “When a private equity firm invests in a company in a highly-regulated space like health care or the life sciences, the firm should be aware of laws and regulations designed to prevent fraud.”

Private equity firms and their counsel should be prepared for heightened FCA scrutiny stemming from their investments in health care companies, and bolster their processes accordingly—both in terms of pre-acquisition diligence and post-acquisition compliance. As Davis’s comments make clear, the government expects nothing less.

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